UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,836	03/04/2005	Kilwon Cho	DE1615.	9374

1109 7590 12/12/2007
ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,836	CHO ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/28/2007 has been entered.

Applicants amendments to the claims filed 09/28/2007 have been entered, applicants have amended claim 1.

Claim Objections

Claim 1 is objected to because of the following informalities: on line 5 of the claim the recitation "functional groups is" is grammatically incorrect, "is" should be deleted by applicants. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claim 8 which claims 9-15 all depend upon is missing the block copolymer represented by formula (1), thereby making the claim indefinite with respect to what applicants are claiming as their invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al. (US 5,702,717).

Cha discloses a system and method for parenteral delivery of a drug (including taxol) in a biodegradable polymer in a liquid composition, the biodegradable polymer is comprised of a block copolymer comprised of a hydrophilic B block comprised of PEG with a MW between about 1000 to 20,000 and a hydrophobic A block comprised of a poly(α-hydroxy acid) polymer, biopolymer or terpolymer which includes poly(d,l-lactide-co-glycolide) i.e. PLA-co-PGA and malic acid with a MW between about 500 and 10,000. See abstract col 7 lin 32-col 8 lin 54, col 10 lin 17-24 and claims. Regarding the limitation that the number of functional groups in the hydrophobic block is between 1-30, since Cha discloses that the hydrophobic block can comprise malic acid (functional group is a carboxylate) and the MW range is so broad (preferably 500-3,000) Cha obviously discloses the same amount of functional groups, for instance 25 malic acid units would have a MW ~2900. The limitation that the composition is a micelle composition is also met because the compositions in Cha are aqueous and the same copolymers will form micelles in the same manner as the same copolymer will inherently form micelles in aqueous solution in the same manner. The limitations of monomers (y) and (z) are also obviously met by the disclosure of Cha who discloses that the hydrophobic A block can contain copolymeric segments containing both PLA-co-PGA, a monomer not containing a side functional group and malic acid which does contain a side functional group (carboxyl). Regarding the limitation that the ratio of z/y is in the range of 0.015 to 2 it is obvious that since the hydrophobic blocks can comprise such a large range of MW (500-10,000) one with skill in the art could vary the amounts of malic acid and PLA-co-PGA so that they could fit within applicants claimed range. For

instance if the MW of PLA-co-PGA was 2,000 and the MW of malic acid was 1,000 the ratio of repeating units containing functional groups (such as malic acid and (z)) to the repeat units that do not contain functional groups (such as PLA-co-PGA and (y)) the ratio would be 0.5 within applicants claimed range. Cha is silent on the ratios of the concentrations of the various hydrophobic bipolymers or terpolymers in relation to one another although it would have been obvious to one skilled in the art to select the ratios claimed through optimizing the types and amounts of each hydrophobic block segment to adjust the degradation rate and interaction between the polymer and drug. See col 10 lin 25-col 11 lin 65. Cha specifically discloses that the degradation rate of the block copolymer can be adjusted by using different poly(hydroxy acid)s which degrade at different rates. It also would be obvious to the skilled artisan that size (molecular weight) of each block would have a further effect on degradation, for instance a longer block would degrade at a slower rate through hydrolysis simply because there are more monomeric units that must be consumed for the entire polymer to completely degrade. Therefore adjusting the types of polymer blocks and their size within the hydrophobic segment would have been obvious for the skilled artisan in order to adjust the degradation properties of the polymer. Cha also discloses that the drug polymer release can be adjusted by the interaction of the drug with the polymer. Thus it would be obvious to the skilled artisan to vary the types of monomers used in the hydrophobic block and their size in order to adjust the interactions with the drug which would affect the overall release of the drug from the gel. For instance blocks with side groups capable of hydrogen bonding such as the carboxylic acid groups on Malic acid would be

capable of hydrogen bonding with active hydrogens on the active ingredient. The stronger the polymer drug interaction the tighter the drug will be held within the polymeric network, thus prolonging drug delivery. Since the hydrophobic portion of the copolymer must contain mostly hydrophobic blocks it would be obvious to the skilled artisan to adjust the amounts of non-functionalized blocks (PLA-PGA) which are more hydrophobic then side functionalized monomers (malic acid) in order to produce an overall block that is hydrophobic in nature. For instance if to many side functionalized monomers are employed in the block (malic acid) the hydrophobic section of the copolymer may be lost, thus the copolymer would no longer have its surfactant like properties. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). Regarding claim 2 the limitation of the weight of the block copolymer compared to the total weight of the composition is met because Cha teaches that the block copolymer concentration can be up to about 50%, which includes applicants claimed range. Regarding the limitation in claim 14 the limitation on the concentration of the drug is met because Cha teaches that

the drug can make up between about 0.1 to 10% by weight of the drug polymer combination. See col 9 lin 28-32. Regarding claims 8 and 9 the Cha patent meets applicants claimed formula because Cha discloses all of the component monomers in the formula of claim 8, that is PEG-PLA-PGA-(malic acid) because as stated above Cha discloses that the hydrophobic block can comprise PLA, PGA, PLA-co-PGA and malic acid biopolymer or terpolymer.

Response to Arguments

Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive. Applicants assert that Cha is designed to administer a hydrophilic drug, in particular a highly water soluble peptide and protein drug which is in contrast to applicants claimed invention which administers a hydrophobic drug. Applicants further assert that the malic acid polymerized block of Cha would have too many functional groups and would not satisfy the specified z/y ratio. Applicants lastly assert an unexpected advantageous result from the features of their copolymers as shown within tables 1 and 2 of the specification. Applicants' assert comparative example 1 corresponds to Cha which shows that the copolymer cannot contain as much drug, releases the drug in a shorter amount of time and degrades over a much longer period then their own copolymers.

The relevance of these assertions is unclear. While Cha does describe peptide or protein based drugs in combination with the copolymers the reference clearly states that other drugs such as taxol can be used in the disclosed compositions. Regarding applicants assertion that Cha does not meet the z/y ratio, the reasoning above is

incorporated herein, that is the ratio could obviously be met by the Cha patent because it describes both functional group containing monomers (malic acid) and non functional group containing monomers (PLA-co-PGA) that can be varied to adjust the degradation rate and the interaction between the polymer and drug. Regarding applicants assertion of unexpected results, clearly from the disclosure of Cha the copolymers can contain the same number of side functional groups in the hydrophobic monomers as applicant's claimed invention. Therefore comparative example 1 does not correspond to the complete scope of Cha, which does disclose functional group containing monomers.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER